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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,334	02/11/2005	Benjamin Oshlack	200.1156US	6951
23280	7590	01/07/2009		
Davidson, Davidson & Kappel, LLC 485 7th Avenue 14th Floor New York, NY 10018			EXAMINER AHMED, HASAN SYED	
			ART UNIT	PAPER NUMBER
			1615	
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			01/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/524,334

Applicant(s)

OSHLACK ET AL.

Examiner

HASAN S. AHMED

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-7 and 10-17 is/are rejected.
7) ☒ Claim(s) 19 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/5508)
Paper No(s)/Mail Date 3/23/06
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Inventor's Patent Application
6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of applicants' amendment/response (filed on 22 September 2008) and IDS (filed on 15 December 2008).

* * * * *

Claim Objections

Claim 19 objected to because of the following informalities: claims 18-52 have been cancelled. Thus the new claim should be claim 53. Appropriate correction is required.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 10-17 remain rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,955,104 ("Mombberger").

Mombberger discloses a pharmaceutical formulation comprising:

- the opioid antagonist (naloxone) of instant claim 1 (see col. 3, line 12);
- the diffusion barrier coating comprising an anionic polymer of instant claim 1 (see col. 2, lines 42-65; col. 4, line 39);
- the coating comprising a hydrophobic material of instant claim 1 (see col. 2, lines 42-65; col. 4, lines 56-59);

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- the opioid antagonist coated over a core of instant claim 2 (see col. 2, lines 42-65; col. 3, line 12);
- the inert bead (core) of instant claim 3 (see col. 2, line 45);
- the dispersed antagonist of instant claim 4 (see col. 3, lines 65-68);
- the methacrylic polymer of instant claim 7 (see col. 4, line 39);
- the diffusion barrier coating (binder) amount of instant claim 10 (see col. 2, line 55);
- the plurality of substrates (pellets) of instant claim 12 (see col. 2, line 43);
- the cellulosic polymer of instant claim 16 (see col. 4, line 57); and
- the naloxone of instant claim 17 (see col. 3, line 12).

The properties recited in instant claims 5, 6, 11, and 13-15 are inherent properties of the claimed composition.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,955,104 ("Mombberger").

Momberger discloses a pharmaceutical formulation (see above). Momberger differs from the instant application in that it does not disclose the particular species of opioid antagonist disclosed in instant claim 19. However, Momberger discloses use of a different opioid antagonist, i.e. naloxone (see col. 3, line 12). Because both naloxone and naltrexone are opioid antagonists, a person of ordinary skill in the art would have been motivated to add either naloxone or naltrexone to the instant formulation. There is a reasonable expectation that the addition of either naloxone or naltrexone to the instant formulation would provide effective opioid antagonism. As such, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add either naloxone or naltrexone to the instant claimed formulation.

* * * * *

Response to Arguments

Applicants arguments filed on 22 September 2008 have been fully considered but they are not persuasive.

1. Applicants argue that, "Momberger states that in the formulation described therein 'the binder solution does **not coat** or embed the active ingredient particles.'..."
See remarks, page 6.

Examiner respectfully submits that Momberger anticipates the instant application as claimed.

Instant claim 1 does not require that active ingredient particles be coated. Rather, the anionic polymer is to coat the substrate. Furthermore, claim 1 does not require that the substrate be completely coated.

Momberger discloses the same amount of anionic polymer as is claimed in instant claim 10 (*i.e.* up to 10%). Furthermore, Momberger discloses spraying of the polymer (binder) on the active (*i.e.* at least partial coating) (*see col. 3, lines 39-40*). Thus, giving the term “coating” its broadest reasonable interpretation, examiner respectfully submits that Momberger anticipates the instant application, as claimed.

2. Applicants argue that the limitation of instant claim 4 is not met because Momberger states that the active ingredient is not embedded in any embedding material or matrix. See remarks, page 6.

Again, examiner respectfully submits that the instant application is anticipated by Momberger as claimed.

Instant claim 4 recites dispersion of agent in matrix multiparticulates. While Momberger does not disclose embedding of an agent in a matrix material, Momberger does not forbid dispersion. In fact, Momberger explicitly discloses dispersion (*i.e.* admixture) of agent with additional materials, such as colloidal silica (*see col. 3, line 66*).

3. Applicants argue that arguments rejecting claims under the theory of inherency (claims 5, 6, 11, and 13-15) are not properly supported. See remarks, page 7.

Instant claim 5 recites an opioid antagonist that is protonated. Naloxone (disclosed by Momberger) is protonated. Instant claim 6 recites a protonated opioid antagonist with affinity for anionic polymer. Since a protonated opioid will be positively charged, it will inherently have affinity for an anionic polymer, which is negatively charged. Instant claims 11 and 13 recite antagonist in a therapeutically effective amount. All pharmaceutical formulations contain therapeutic agents in a therapeutically

effective amount, otherwise the formulation will have no purpose. As for claims 14 and 15, controlled release and sequestration are inherent properties of hydrophobic materials.

* * * * *

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

This application contains claims 8 and 9 drawn to an invention nonelected with traverse in the reply filed on 14 April 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HASAN S. AHMED whose telephone number is (571)272-4792. The examiner can normally be reached on 9am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/H. S. A./
Examiner, Art Unit 1618

/Humera N. Sheikh/
Primary Examiner, Art Unit 1615

